

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Jan Peter Sternby

Serial No.: 10/533,251

Filed: April 29, 2005

Title: A Method and an Apparatus for Determining the Efficiency of Dialysis

Attorney Docket No.: 12710-00001

Group Art Unit: 3761

Confirmation No.: 7073

Examiner: Leslie R. Deak

Mail Stop 16  
Director of the USPTO  
P.O. Box 1450  
Alexandria, VA 22313-1450

October 31, 2008

**REQUEST FOR REFUND**

On August 19, 2008, the U.S. Patent and Trademark Office (USPTO) debited Deposit Account 04-1588 of the undersigned's law firm in the amount of \$100.00 in connection with the above-referenced patent application. It is respectfully submitted that the USPTO deducted this amount in error.

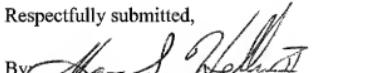
In response to a final Office Action, on August 12, 2008, the undersigned filed an Amendment and Request for Continued Examination (RCE) relative to the above-identified application. As indicated on the Transmittal Sheet (attached hereto as Exhibit A) that accompanied that Amendment and RCE, the total number of claims remaining after the amendment is 19, with 4 of those claims being independent claims. However, the attached Patent Application Fee Determination Record (PAFDR) (attached hereto as Exhibit B) shows a total of "24" claims remaining after amendment. Applicant respectfully disagrees with the total of 24 shown on the PAFDR.

As seen in the Amendment (attached hereto as Exhibit C), there were clearly 19 claims remaining after the amendments made therein. Specifically, claims 1-10, 15, 16 and 18-24

remain after the amendments of the August 12, 2008, filing. As clearly indicated in the Amendment, claims 11-14 and 17 had been previously canceled, and therefore the USPTO should not have included them in the total of the claims. Since only 19 claims actually remain, the USPTO should not have debited Deposit Account No. 04-1588 for the \$100 fee that the USPTO is attributing (erroneously) to additional total claims over the number previously paid for. It would appear that the error occurred because the USPTO did not acknowledge the fact that Claims 11-14 and 17 were previously canceled.

Regardless of how the error occurred, the undersigned respectfully requests that a refund in the amount of \$100.00 be credited to Deposit Account No. 04-1588. If any question remains, the USPTO is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

By   
\_\_\_\_\_  
Morgan S. Heller II  
Registration No. 44,756

DOWNS RACHLIN MARTIN PLLC  
Tel: (802) 863-2375  
Attorneys for Assignee

2861741.1

## EXHIBIT A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Jan Peter Sternby

Serial No.: 10/533,251

Filed: April 29, 2005

Title: A Method And An Apparatus For Determining The Efficiency Of Dialysis

Attorney Docket No.: 12710-00001 (New)  
(5049.0002) (Old)

Group Art Unit: 3761

Confirmation No.: 7073

Examiner: Leslie R. Deak

Commissioner for Patents  
Alexandria, VA 22313-01450

August 12, 2008

**Transmittal for Power of Attorney and Change of Correspondence Address, RCE,  
Amendment and Response and Request for Extension of Time**

Transmitted herewith for filing is a Power of Attorney and Change of Correspondence Address, Request for Continued Examination, Amendment and Response to Final Office Action dated April 25, 2008, and Request for Extension of Time, with regard to the above-identified Application;

CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL 19	MINUS	20	= 0	x \$50.00/=	\$00
INDEPENDENT 4	MINUS	3	= 1	x \$210.00/=	\$210.00
				TOTAL	\$210.00

REQUEST FOR EXTENSION OF TIME

This is a petition to extend by one (1) month the shortened statutory period for response to the Office Action for the above-identified application mailed on April 25, 2008. With this extension the new period for response expires on August 25, 2008.

1. Applicant is:

- other than a small entity.  
 a small entity.

2. Extension period and fee:                   Large Entity

one month                   \$120.00

=====

Fee:                   \$120.00

FEE PAYMENT

- The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 04-1588.
- Any additional filing fees required under 37 C.F.R. §1.16.
- Any patent application processing fees under 37 C.F.R. §1.17.

Respectfully submitted,

DOWNS RACHLIN MARTIN PLLC

By:



Morgan S. Heller II

Attorney of Record

Registration No.: 44,756

557946.2

P249-12/00

Page 2 of 2

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## **EXHIBIT B**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875			Application or Docket Number 10/533,251	Filing Date 04/29/2005	<input type="checkbox"/> To be Mailed		
APPLICATION AS FILED – PART I							
	(Column 1)	(Column 2)	SMALL ENTITY <input type="checkbox"/>	OR	OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEES (\$)	RATE (\$)		
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (e), or (g))	N/A	N/A	N/A		N/A		
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(l), (j), or (m))	N/A	N/A	N/A		N/A		
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A		N/A		
TOTAL CLAIMS (37 CFR 1.16(n))	minus 20 =	*	X \$ =		X \$ =		
INDEPENDENT CLAIMS (37 CFR 1.16(n))	minus 3 =	*	X \$ =		X \$ =		
If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(e).							
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(e))							
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL		TOTAL		
APPLICATION AS AMENDED – PART II							
	(Column 1)	(Column 2)	(Column 3)	SMALL ENTITY	OTHER THAN SMALL ENTITY		
<b>AMENDMENT</b>  <b>08/12/2008</b>	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(g))	- 24	Minus ** 22	= 2	X \$ =	OR X \$ 50=	100
	Independent (37 CFR 1.16(n))	- 4	Minus *** 3	= 1	X \$ =	OR X \$ 210=	210
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(e))						
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
				TOTAL ADDL FEE		TOTAL ADDL FEE	310
	(Column 1)	(Column 2)	(Column 3)	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)
<b>AMENDMENT</b>	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	X \$ -		X \$ -	
	Total (37 CFR 1.16(g))	-	Minus **	=	X \$ =		
	Independent (37 CFR 1.16(n))	-	Minus ***	=	X \$ =		
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(e))						
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
				TOTAL ADDL FEE		TOTAL ADDL FEE	

\* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.  
 \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".  
 \*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:  
/Ruby Johnson/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

## EXHIBIT C

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Jan Peter Sternby

Serial No.: 10/533,251

Filed: April 29, 2005

Title: A Method And An Apparatus For Determining The Efficiency Of Dialysis

Attorney Docket No.: 12710-00001 (New)  
(5049.0002) (Old)

Group Art Unit: 3761

Confirmation No.: 7073

Examiner: Leslie R. Deak

Commissioner for Patents  
Alexandria, VA 22313-1450

August 12, 2008

**AMENDMENT AND RESPONSE ACCOMPANYING FIRST RCE**

This is in response to the Office Action (paper no. 20080423) mailed from the United States Patent and Trademark Office on April 25, 2008, with respect to the above-identified application.

A Status of the Claims starts on the following page 2.

Remarks concerning the Office Action start on the following page 9.

## STATUS OF THE CLAIMS

The status of the claims of the current application stands as follows:

1. **(Currently Amended)** A method of estimating a process efficiency of a dialysis system comprising a dialyzer, wherein said dialyzer is connected to a patient's blood system for performing a dialysis treatment of the patient, said dialyzer having a potential cleaning clearance capacity ( $K_{eff}$ , K), wherein said method comprises:  
determining a whole body clearance ratio ( $K_{wb}/K_{eff}$ ,  $K_{wb}/K$ ) defining the patient's response to value representing a whole body clearance of the patient divided by the potential cleaning clearance capacity (K<sub>eff</sub>, K), the whole-body-clearance ratio being a dimensionless positive numeral smaller than one of the dialyzer.
2. **(Currently Amended)** A method according to claim 1, wherein the step of determining the whole body clearance ratio ( $K_{wb}/K_{eff}$ ,  $K_{wb}/K$ ) value comprises:  
measuring a final blood urea concentration no later than approximately one minute after the end of a dialysis treatment;  
measuring an equilibrated blood urea concentration no earlier than approximately one half hour after the end of the dialysis treatment; and  
dividing said final blood urea concentration by said equilibrated blood urea concentration so as to obtain the whole body clearance ratio value.
3. **(Currently Amended)** A method according to claim 2, wherein said measuring of said final blood urea concentration is measured includes measuring said final blood urea concentration immediately after the end of the dialysis treatment to obtain the whole-body-clearance ratio ( $K_{wb}/K$ ) with respect to a dialyzer clearance (K).
4. **(Currently Amended)** A method according to claim 2, wherein said measuring of said final blood urea concentration is measured includes measuring said final blood urea concentration

approximately one minute after the end of the dialysis treatment to obtain the whole-body clearance ratio ( $K_{wb}/K_{eff}$ ) with respect to an effective clearance ( $K_{eff}$ ).

5. **(Currently Amended)** A method according to claim 1, wherein the step of determining the whole body clearance ratio ( $K_{wb}/K_{eff}$ ,  $K_{wb}/K$ ) value comprises of:  
measuring an initial urea concentration ( $C_{d0}$ ,  $C_{b0}$ );  
measuring at least two subsequent urea concentration values at spaced time intervals after the dialysis treatment has started, a first value of said at least two values being measured no earlier than approximately one-half hour after the dialysis treatment has started;  
deriving a starting urea concentration based on an extrapolation in time of said at least two values back to the start of the dialysis treatment; and  
dividing said starting urea concentration by said initial urea concentration ( $C_{d0}$ ,  $C_{b0}$ ).
6. **(Currently Amended)** A method of estimating a whole body clearance ratio ( $K_{wb}/K_{eff}$ ) value, with respect to an effective clearance ( $K_{eff}$ ), of a dialysis treatment of a patient, said whole body clearance ratio ( $K_{wb}/K_{eff}$ ) value defining a response by the patient to a potential cleaning clearance capacity ( $K_{eff}$ ) of a dialyzer performing the dialysis treatment, comprising:  
determining the whole body clearance ratio ( $K_{wb}/K_{eff}$ )-with respect to the effective clearance ( $K_{eff}$ ) value so as to represent a whole body clearance divided by an effective clearance of the dialysis treatment, the whole body clearance ratio value being based on a measurement of a slope ( $K_{wb}/V$ ) of a logarithmic removal rate function ( $C_d$ ,  $C_b$ ), said function corresponding to a lowering of a urea concentration during the dialysis treatment; the whole body clearance ratio being a dimensionless positive numeral smaller than one.
7. **(Currently Amended)** A method according to claim 6, further comprising:  
determining an initial dialysate urea concentration ( $C_{d0}$ );

- determining a total flow rate ( $Q_d$ ) of spent dialysate during the dialysis treatment, said dialysis treatment including any ultrafiltration;
- calculating, based on measurements performed during a steady state phase ( $t_3-t_4$ ) of the treatment, the slope ( $K_{wb}/V$ ) of said logarithmic removal rate function ( $C_d$ );
- measuring a predialysis urea mass ( $m_0$ ); and
- determining the whole body clearance ratio ( $K_{wb}/K_{eff}$ ), ~~with respect to the effective clearance ( $K_{eff}$ )~~, value as a product of said slope ( $K_{wb}/V$ ) and said predialysis urea mass ( $m_0$ ), divided by said total flow rate ( $Q_d$ ) and divided by said initial dialysate urea concentration ( $C_{d0}$ ).
8. (Currently Amended) A method according to claim 6, further comprising:
- calculating, based on measurements performed during a steady state phase ( $t_3-t_4$ ) of the dialysis treatment, the slope ( $K_{wb}/V$ ) of said logarithmic removal rate function ( $C_d, C_b$ );
- determining an entire distribution volume (V); and
- determining the whole body clearance ratio ( $K_{wb}/K_{eff}, K_{wb}/K$ ) value as the product of said slope ( $K_{wb}/V$ ) and said entire distribution volume (V) divided by the potential cleaning capacity ( $K_{eff}, K$ ).
9. (Previously Presented) A method according to one of claims 7 or 8, wherein the slope ( $K_{wb}/V$ ) of said logarithmic removal rate function ( $C_d$ ) is measured on a dialysate side of a dialysis system comprising the dialyzer.
10. (Previously Presented) A method according to claim 8, wherein the slope ( $K_{wb}/V$ ) of said logarithmic removal rate function ( $C_b$ ) is measured on a blood side of a dialysis system comprising the dialyzer.

Claims 11-14: (Canceled).

15. (Currently Amended) A method of performing a dialysis treatment program by a dialyzer, said method comprising the steps of:
- performing a first dialysis treatment of the patient under a first set of conditions which include at least one of a treatment time and a composition of dialysate in the dialyzer; estimating, during the first dialysis treatment, a whole body clearance ratio ( $K_{wb}/K_{eff}$ ,  $K_{wb}/K$ ) value according to one of claims 2 to 6;
- comparing the whole body clearance ratio ( $K_{wb}/K_{eff}$ ,  $K_{wb}/K$ ) value to a threshold ratio value; and
- performing a dialysis treatment of the patient after said first dialysis treatment under a second set of conditions which are different from the first set of conditions, if the whole body clearance ratio ( $K_{wb}/K_{eff}$ ,  $K_{wb}/K$ ) value is less than the threshold ratio value.
16. (Currently Amended) An apparatus ~~configured to estimate a whole body clearance ratio of a dialysis treatment of a patient, the whole body clearance ratio ( $K_{wb}/K_{eff}$ ), with respect to an effective clearance ( $K_{eff}$ ), defining a response to a potential cleaning capacity of a dialyzer performing the dialysis treatment, said apparatus comprising:~~
- a urea monitor circuit configured to determine an initial dialysate urea concentration ( $C_{d0}$ ), determine a total flow rate ( $Q_d$ ) of spent dialysate during the dialysis treatment including any ultra filtration, measure, during a steady state phase ( $t_3-t_4$ ) of the dialysis treatment, a slope ( $K_{wb}/V$ ) of a removal rate function corresponding to a lowering of a dialysate urea concentration during the dialysis treatment, and measure a predialysis urea mass ( $m_0$ ); and
- a processor configured to determine the ~~a~~ whole body clearance ratio ( $K_{wb}/K_{eff}$ ) value for the patient, ~~the said~~ whole body clearance ratio ( $K_{wb}/K_{eff}$ ) ~~with respect to the representing a whole body clearance of the patient divided by an effective clearance ( $K_{eff}$ )~~, being determined as the product of said slope ( $K_{wb}/V$ ) and said predialysis urea mass ( $m_0$ ),

divided by said flow rate ( $Q_d$ ) and divided by said initial dialysate urea concentration ( $C_{d0}$ ), the whole body clearance ratio being a dimensionless positive numeral smaller than one.

17. (Cancelled).

18. (New) A computer-readable medium containing computer-executable instructions for performing a method of estimating a process efficiency of a dialysis system comprising a dialyzer, wherein the dialyzer is connected to a blood system of a patient for performing a dialysis treatment of the patient and the dialyzer has a potential clearance capacity, the computer-executable instructions comprising:  
a set of computer-executable instructions for determining a whole body clearance ratio value representing a whole body clearance of the patient divided by the potential clearance capacity of the dialyzer.

19. (New) A computer-readable medium according to claim 18, wherein said set of computer-executable instructions includes:  
computer-executable instructions for receiving a final blood urea concentration measured no later than approximately one minute after the end of a dialysis treatment;  
computer-executable instructions for receiving an equilibrated blood urea concentration measured no earlier than approximately one half hour after the end of the dialysis treatment;  
computer-executable instructions for dividing said final blood urea concentration by said equilibrated blood urea concentration so as to obtain the whole body clearance ratio value; and  
computer-executable instructions for displaying the whole body clearance ratio value along with an indication that the whole body clearance ratio value is a whole body clearance ratio.

20. (New) A computer-readable medium according to claim 18, wherein said set of computer-executable instructions includes:
- computer-executable instructions for receiving an initial measured urea concentration;
- computer-executable instructions for receiving at least two subsequent measured urea concentration values at spaced time intervals after the dialysis treatment has started, a first value of the at least two measured urea concentration values being measured no earlier than approximately one-half hour after the dialysis treatment has started;
- computer-executable instructions for deriving a starting urea concentration based on an extrapolation in time of said at least two values back to the start of the dialysis treatment; and
- computer-executable instructions for dividing the starting urea concentration by the initial urea concentration.
21. (New) A computer-readable medium according to claim 18, wherein said set of computer-executable instructions includes:
- computer-executable instructions for measuring a slope of a logarithmic removal rate function corresponding to a lowering of a urea concentration during the dialysis treatment; and
- computer-executable instructions for calculating the whole body clearance ratio value based on the slope of the logarithmic removal rate function.
22. (New) A computer-readable medium according to claim 21, wherein said set of computer-executable instructions includes:
- computer-executable instructions for receiving an initial dialysate urea concentration;
- computer-executable instructions for receiving a total flow rate of spent dialysate during the dialysis treatment, the dialysis treatment including any ultrafiltration;
- computer-executable instructions for calculating, based on measurements performed during a steady state phase of the treatment, the slope of the logarithmic removal rate function;
- computer-executable instructions for receiving a predialysis urea mass; and

- computer-executable instructions for calculating the whole body clearance ratio value as a product of the slope and said predialysis urea mass, divided by the total flow rate and divided by the initial dialysate urea concentration.
23. (New) A computer-readable medium according to claim 22, wherein said set of computer-executable instructions further includes computer-executable instructions for displaying the whole body clearance ratio value along with an indication that the whole body clearance ratio value is a whole body clearance ratio.
24. (New) A computer-readable medium according to claim 21, wherein said set of computer-executable instructions includes:  
computer-executable instructions for calculating, based on measurements performed during a steady state phase of the dialysis treatment, the slope of said logarithmic removal rate function;  
computer-executable instructions for determining an entire distribution volume; and  
computer-executable instructions for determining the whole body clearance ratio value as the product of the slope and the entire distribution volume divided by the potential cleaning capacity.

## REMARKS

Claims 1-10, 15, 16 and 18-24 are pending in the current application. Claims 11-14 and 17 were canceled previously. Claims 1-8, 15 and 16 are amended herein. Claims 18-24 have been added.

Applicant respectfully request reconsideration of the application in view of the foregoing amendments and the remarks appearing below.

### Request for Examiner Interview

Applicant respectfully requests a telephonic Examiner Interview between the Examiner and the below-signed attorney, Morgan Heller II. Mr. Heller II will contact the Examiner to set up the Interview in due time. The U.S. Patent and Trademark Office (USPTO) is respectfully requested to refrain from deciding whether or not to reject the presently amended claims until after the Interview so that the Examiner can consider the issues discussed in the Interview.

### Comments on the USPTO's Responses to Applicant's Prior Arguments

On pages 5-7 of the current Office Action, the USPTO presents responses to Applicant's arguments filed on February 26, 2008. Applicant wishes to take an opportunity, prior to addressing the claim rejections in detail, to respond to some of those responses.

Regarding the response in item 9 of the current Office Action, the USPTO states that "In the instant case, Sternby discloses that the whole body clearance ratio, K, may be calculated from the disclosed variables, and does not disclose that those variable are unattainable." [Emphasis added.] This statement demonstrates to Applicant that the USPTO is (improperly) blurring the distinction between "whole body clearance" (which in the Sternby publication is denoted "K") and a "whole body clearance ratio," which the current application, including the claims, clearly define as a ratio of two clearances, namely, a whole body clearance to a potential clearance capacity of a dialyzer. When the USPTO recognizes there is a significant distinction between the two terms, Applicant is confident the USPTO will realize the error in the present rejections.

Regarding the response in item 8 of the current Office Action, the USPTO states that “Applicant’s claim language merely relates whole body clearance to the cleaning capacity without actually using the values of the cleaning capacity to generate the clearance ratio. Accordingly, Sternby suggests the calculation of the clearance ratio as claimed by Applicant.”

Applicant believes the above-quoted statement of the USPTO is driven by the misapprehension by the USPTO of the difference between a “clearance” and a “clearance ratio” as mentioned above and discussed below in detail. Applicant respectfully submits that, while the Sternby publication mentions various clearances, i.e., whole body clearance and effective clearance, the Sternby publication is completely silent on determining a clearance ratio. Therefore, the assertion in item 8 of the current Office Action is not correct even with respect to the claims as they stood prior to the current amendments. The originally filed claims required determination of a clearance ratio, and the Sternby publication clearly does not disclose such a ratio of clearances.

In addition, the statement that “Applicant’s claim language merely relates whole body clearance to the cleaning capacity without actually using the values of the cleaning capacity to generate the clearance ratio” appears to misperceive the present invention. In some embodiments of the present invention, including explicitly claimed embodiments, Applicant has disclosed ways to determine whole body clearance ratios (i.e.,  $K_{wb}/K$  and  $K_{wb}/K_{eff}$ ) without directly using values for the potential clearance capacities  $K$  and  $K_{eff}$ . Rather, the ratios themselves (as opposed to the individual clearances that constitute the ratio) can be estimated without actually determining values of the clearances  $K_{wb}$ ,  $K$  and  $K_{eff}$ . See, e.g., the right hand sides of the equations in paragraphs [0040] and [0057] (these paragraph identifiers appear in the publication of the current application) that show ways of calculating whole body clearance ratios without directly calculating the constituent clearances. These ways are useful because they avoid otherwise difficult or impractical calculations. Herein lies an important benefit of Applicant’s invention. So, in fact, ones of the current claims do not actually use values of  $K$  and  $K_{eff}$  to calculate the ratios as the USPTO appears to be suggesting is required to define over the Sternby publication.

### **Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 1, 6 and 16 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the USPTO states that the language added in a prior response to the effect that the whole body clearance ratio is a dimensionless positive numeral smaller than one is unsupported by the specification as originally filed.

Applicant has removed the referenced language. Therefore, the present rejection is moot, and Applicant respectfully requests withdrawal of the present rejection.

While the present rejection is now moot, Applicant respectfully submits that the phrase in question (now deleted) would indeed satisfy the written description requirement. In particular, when the claim term “whole body clearance ratio” is given its proper meaning in light of the specification, i.e., that “whole body clearance ratio” means a ratio of a whole body clearance to a potential clearance capacity of a dialyzer, it is clear to those having ordinary skill in the art that the result is dimensionless. A clearance divided by a clearance, i.e., K<sub>1</sub>/K<sub>2</sub>, has no dimensions because the dimensions of K<sub>1</sub> in the numerator and the like dimensions of K<sub>2</sub> in the denominator cancel one another. Further, since it is well-known that a body clearance, such as a whole body clearance, will, in actual practice, always be less than the potential clearance capacity of the dialyzer because of the practical limits of dialysis in achieving an actual body clearance equal to the theoretical clearance potential of the dialyzer (which would result in a ratio of 1), those of ordinary skill in the art will instantly recognize that the ratio of the body clearance to potential clearance capacity will always be less than 1.

The USPTO is reminded that there is no *in haec verba* requirement for a newly added claim limitation to meet the written description requirement of 35 U.S.C. § 112. See, e.g., MPEP § 2163.I.B. Rather, the newly added limitation can meet the written description requirement if it is implicitly or inherently disclosed in the original specification. *Id.* In the present case, Applicant respectfully submits that anyone having ordinary skill in the art and properly understanding “whole body clearance ratio” to be a ratio of whole body clearance to potential clearance capacity, will readily understand that the original version of the current application

implicitly discloses that the whole body clearance ratio will be both less than one and a dimensionless value. Therefore, Applicant respectfully submits that the present rejection would have been improper had the phrase at issue remained in the claims.

**Rejection Under 35 U.S.C. § 103**

*Sternby*

Claims 1-10, 12 and 14-16 stand rejected under 35 U.S.C § 103(a) as being obvious in view of International Application Publication No. 98/55166 to Sternby (hereinafter, "the Sternby Publication"). Applicant respectfully disagrees.

In the cited publication, Sternby discloses a method and apparatus for calculating the mass of a composition in a fluid volume and for calculating efficiency of exchange of the composition with an exchange fluid. Importantly, and as discussed further below, the Sternby publication does not disclose or suggest the determining of values of whole body clearance ratios as claimed in the amended claims and, indeed, as claimed in the original claims.

In this connection, Applicant desires to point out that the calculated measures in the Sternby publication (i.e., K/V and  $K_e/V$ ) are completely different from, and are not equivalent to, the calculated measures in the current application (i.e.,  $K_{wb}/K_{eff}$  and  $K_{wb}/K$ ). The measures K/V and  $K_e/V$  of the Sternby publication relate treatment efficiency to the size of the patient, whereas the inventive measures  $K_{wb}/K_{eff}$  and  $K_{wb}/K$  of the current application relate treatment efficiency to a theoretical maximum efficiency. A useful distinction between the two differing sets of measures is that the measures of the Sternby reference can be increased simply by prolonging a treatment session, whereas the measures of the present invention cannot be increased by prolonging a treatment session. An important use of the treatment-length independence aspect of the measures of the present invention in the context of dialysis is that these measures can be used in determining adjustments to dialysis parameters other than session length. Such a benefit eluded skilled artisans prior to the present invention.

In the present rejection, the USPTO makes several assertions that are not accurate and that lead Applicant to believe the rejection is misguided.

First, and as touched on above, the USPTO asserts that the Sternby publication discloses the concept of a whole body clearance ratio. This is not true. The Sternby publication discloses the concept of whole body clearance, which, as well-known in the art, is defined as the ratio removal rate to equilibrated concentration in the subject's body. Whole body clearance is typically denoted by "K," "K<sub>wb</sub>" or other similar identifier. See, e.g., the background section of the current application and page 10, lines 18-20 of the Sternby publication for support for the meaning of "clearance." In other words, by definition, whole body clearance is a ratio. Thus, to say "whole body clearance ratio" when referring to a whole body clearance (K<sub>wb</sub>) is improper because the whole body clearance is a ratio. That is, the word "ratio" in the term "whole body clearance ratio" is redundant because the term "ratio" is inherently part of the definition of whole body clearance. This is akin to saying "the ratio ratio," which is nonsensical. Thus, the term "whole body clearance ratio" must mean something other than just "whole body clearance." In fact, it does, and this meaning is clearly provided by the current specification as originally filed.

In particular and as provided by the current specification, a whole body clearance ratio is a ratio of whole body clearance (here, denoted K<sub>wb</sub>) to a clearance capacity of a dialyzer (here, either K or K<sub>eff</sub>). Clearly, the Sternby publication does not disclose or suggest determining a ratio of two clearances, let alone the particular ways to calculate the ratio that appear in various ones of the rejected claims.

Second, the USPTO asserts on page 3 of the current Office Action that the method disclosed in the Sternby publication "is capable of generating a clearance ratio within the values set forth by applicant." Applicant believes the USPTO is asserting that the whole body clearance or effective clearance, or both, disclosed in the Sternby publication could have values less than one and are dimensionless. This simply is not so because clearances (again, which the USPTO is improperly calling "clearance ratios") are not dimensionless. Because clearances are defined as removal rate (e.g., mass/time) divided by concentration (e.g., mass/volume), their dimensions are volume/time. In contrast, it is clearly seen that the whole body clearance "ratios" of the present claims, which are defined as a first type of clearance (volume/time) divided by a second type of clearance (also, volume/time) are truly dimensionless.

Turning now to the claims in detail, amended independent claim 1 now requires “determining a whole body clearance ratio ( $K_{wb}/K_{eff}$ ;  $K_{wb}/K$ ) value representing a whole body clearance of the patient divided by the potential clearance capacity ( $K_{eff}$ ;  $K$ ) of the dialyzer.” [Emphasis added.] Consequently, amended claim 1 (and its dependent claims) now explicitly define the whole body clearance ratio as whole body clearance divided by potential clearance capacity of the dialyzer. In this connection, Applicant notes that in item 8 on page 6 of the current Office Action the USPTO states that “the Applicant does not actually claim the steps of determining the whole body clearance ratio based on or using the values of the potential cleaning capacity.” [Emphasis in original.] Applicant respectfully submits that the current amendment to claim 1 rectifies any perceived issue in this regard. (That said, Applicant believes that the fact that the term “whole body clearance ratio” is effectively defined in the present application as being a ratio of clearances obviates the need for the present amendment.)

Regarding the change from “cleaning capacity” to “clearance capacity,” those skilled in the art will readily understand that “cleaning” and “clearance” in the present context are synonymous. Applicant has made the change to further emphasize that the resulting ratio is indeed a dimensionless value as discussed above. It is Applicant’s position that the above-quoted step of amended claim 1 is clearly not disclosed or suggested by the Sternby publication.

Because the Sternby publication does not disclose or suggest the above-quoted step of amended claim 1 and no other reference of record discloses or suggests that step, amended claim 1 cannot be obvious in view of the Sternby publication, nor can claims 2-5 that depend therefrom.

Regarding independent claim 6, this claim has been amended to similarly require the step of “determining the whole body clearance ratio ( $K_{wb}/K_{eff}$ ) value so as to represent a whole body clearance divided by an effective clearance of the dialysis treatment.” [Emphasis added.] Consequently, the present rejection is improper for amended claim 6 (and its dependent claims 7-10) in the same manner it is improper for claim 1.

Regarding claim 15, this claim relies on either one of amended independent claims 1 and 6. Therefore, it, too, is patentable over the Sternby publication for at least the reasons discussed above relative to amended claims 1 and 6.

Regarding independent claim 16, this claim as amended requires, among other things, “a processor configured to determine a whole body clearance ratio ( $K_{wb}/K_{eff}$ ) value for the patient, said whole body clearance ratio ( $K_{wb}/K_{eff}$ ) representing a whole body clearance of the patient divided by an effective clearance.” [Emphasis added.] Applicant respectfully submits that this limitation explicitly defines the whole body clearance ratio to include the effective clearance in the denominator so as to require the ratio to be a dimensionless number. Consequently, amended claim 16 is patentable over the Sternby publication for at least the same reasons discussed above relative to amended claim 1.

In addition to all of the pending claims being patentable over the Sternby publication for the reasons just discussed, Applicant respectfully submits that the various specific processes for directly calculating whole body clearance ratios, i.e.,  $K_{wb}/K$  and  $K_{wb}/K_{eff}$  (again, as distinguished from a clearance itself (e.g., K)), appearing in many of the claims, such as in claims 2-10, 15 and 16, are separately patentable relative to the patentability discussed above. This is so at least because even though the Sternby publication may disclose such generic tasks as measuring urea concentrations, taking blood samples, using slope of a concentration curve to find an initial urea mass, none of these tasks are used in determining a whole body clearance ratio. Therefore, these claims cannot be rendered obvious by the Sternby publication.

For at least the foregoing reasons, Applicant respectfully requests withdrawal of the present rejection.

#### Patentability of New Claims 18-24

New claims 18-24 are “Beauregard claims” directed to computer-readable media containing computer executable instructions that perform various steps of method claims 1, 2 and 5-8. Applicant respectfully submits that new claims 18-24 are patentable over the references

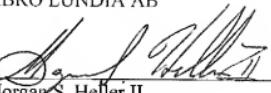
of record for the same reasons that claims 1, 2 and 5-8 are patentable over the references of record.

**CONCLUSION**

In view of the foregoing, Applicant respectfully submits that claims 1-10, 15, 16 and 18-24, as amended and newly added, are in condition for allowance. If any issues remain, the Examiner is encouraged to call the undersigned attorney at the number listed below.

Respectfully submitted,

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